

REMARKS

Claims 1-40 constitute the pending claims in the present application. Applicants respectfully request reconsideration in view of the following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the prior Office Action.

1-4. Applicants note that the previous amendment was entered and considered, and that claims 1-13 and 23-36 are withdrawn as being directed to a non-elected invention. Applicants will cancel such claims upon indication of allowable subject matter.

5. Applicants note that item BX on the previous IDS was not considered. This item will not be resubmitted.

6. Claims 14-22 and 37-40 are rejected under 35 U.S.C. § 101 because the claimed invention allegedly lacks patentable utility. Applicants respectfully traverse this rejection.

The Advisory Action states that Faye et al., discussed in detail below, has not been considered because it published after the priority date of the present application. Applicants respectfully point out, however, that the law makes no such distinction. MPEP 2107.03, which permits the filing of data to rebut a rejection under 35 U.S.C. § 101, inherently supports this position, since such data need not have been known in the prior art nor have been provided in the application as filed. The Federal Circuit has endorsed this approach, reversing an examiner's rejection on utility and enablement grounds based on a declaration provided during prosecution demonstrating that the compounds possessed the antitumor activity alleged in the application. *In re Brana*, 51 F.3d 1560, 34 USPQ 1436 (Fed. Cir. 1995).

Even the Utility Training Materials used in the Patent and Trademark Office follow this approach. Applicants direct the Examiner's attention to Example 11, page 61, in which Applicants respond to a utility rejection with a declaration supporting the asserted utility of one of the claimed inventions. The Materials state that "[t]he examiner should withdraw the rejection ... in light of this evidence." Although Applicants recognize that Faye et al. is not a declaration, evidence of this type is routinely used interchangeably with declarations under 37 C.F.R. § 132 to provide evidence in support of the enablement or utility of claimed subject matter. The case

law and administrative documents discussed above merely demonstrate that the availability of such evidence before the filing date of an application is not necessary for its consideration and successful rebuttal of a utility rejection.

Faye et al., WO 99/07836, cited as reference BV in the IDS filed January 29, 2001, discloses nucleotide and amino acid sequences with strong similarity to SEQ ID Nos. 13 and 14. For example, SEQ ID No. 2 of Faye et al. differs from SEQ ID No. 14 of the present application by merely six amino acids, 98% identity (see sequence comparison previously submitted as Exhibit A). On page 8, lines 30-36, Faye et al. state that cells transformed by a plasmid encoding SEQ ID No. 2 (CaCIV1) rescues *S. cerevisiae* cells which lack a functional ScCIV1 gene, a gene essential for cell viability. Accordingly, an agent which blocks the function of CaCIV1 would be expected to exhibit antifungal activity. Applicants asserted that the claimed subject matter was useful for drug screening assays on page 4, lines 5-6, and page 9, lines 11-18, and Faye et al. demonstrate the accuracy of these assertions.

The Advisory Action further states that "the CAK1 utility in diagnostic tool has not been asserted in the specification." Applicants submit that use as a diagnostic tool, despite the Office Action's assertions to the contrary, is a *specific and substantial* utility that was asserted in the present application. The application asserts this utility at the top of page 4 and the first full paragraph on page 9, as well as the paragraph bridging pages 15 and 16 and lines 17-29 of page 25. The last of these passages points *specifically* to CAK1, SEQ ID No. 13, contrary to the Examiner's assertions in the Advisory Action. The mere fact that other sequences may also be used for this purpose does not contradict this utility, or make it any less specific. For example, many different compounds have been identified – and patented – as antidepressant pharmaceuticals. The mere fact that *one* antidepressant is known does not make subsequent compounds identified as having similar activity any less useful, nor their utility any less specific, as the arguments recited in the Office Action suggest. Accordingly, the mere fact that other nucleic acids identified and sequenced from *C. albicans* could be used for diagnostic purposes does not undercut the fact that the presently claimed subject matter could also be used to diagnose the presence of *C. albicans* in a patient. Contrary to the statements in the Office Action, it is not true that *any* nucleic acid would have this utility. This utility is dependent on the

particular sequence disclosed by Applicants, and random sequences would typically be ineffective for this purpose. This fact demonstrates that the asserted utility is, in fact, specific.

For the reasons set forth above, Applicants submit that the pending claims fully comply with the requirements of 35 U.S.C. § 101. Reconsideration and withdrawal of this rejection is respectfully requested.

With respect to the rejection of these claims as not being enabled because the claimed invention was not allegedly supported by a utility, Applicants submit that the uses described above were described in the application with sufficient detail and clarity that one of skill in the art could have practiced the claimed invention throughout its scope. Reconsideration and withdrawal of this rejection is respectfully requested.

7. Claims 37-40 are rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants respectfully traverse this rejection to the extent it is maintained over the claims as amended.

Applicants have amended claim 37 to more particularly point out conditions recited on page 13 of the application. Reconsideration and withdrawal of this rejection is respectfully requested.

8. Claims 37-40 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. Applicants respectfully traverse this rejection to the extent it is maintained over the claims as amended.

Applicants have amended claim 37 as pointed out above. Applicants submit that hybridization is a common laboratory technique, and that one of skill in the art would readily be able to determine whether or not a nucleic acid sequence hybridizes to another under specified conditions. Reconsideration and withdrawal of this rejection is respectfully requested.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000. Should an extension of time be required, Applicants hereby petition for same and request that the extension fee and any other fee required for timely consideration of this submission be charged to Deposit Account No. 18-1945.

Respectfully Submitted,

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